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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/761,782

Applicant(s)

LIVSHITS ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-19 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8 and 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 11, mailed on October 22, 2002), Applicants filed an amendment and response received on March 20, 2003 (Paper No. 14). Said amendment cancelled Claim 3, amended Claims 1, 2, and 4-6, and added new Claims 10-19. Thus, Claims 1, 2, and 4-19 are pending in the instant Office action.

Election

2. Claim 9, previously withdrawn from consideration as a non-elected invention, remains withdrawn from consideration. Claim 19 is also withdrawn from consideration in the instant Office action for the same reasons.

Claims 1, 2, 4-19 are pending, Claims 9 and 19 are withdrawn from consideration as non-elected invention, and Claims 1, 2, 4-8, and 10-18 will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the foreign application 2000101678 filed in Russia on January 26, 2000.

Drawings

4. As previous noted, the drawings filed on July 3, 2001 (Paper No. 6) had been approved by the Draftsmen. However, amendments to the drawings (Figure 2) were filed in response to the previous Office action (Paper No. 11); said amendment was filed only in red ink. A new,

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complete set of formal drawings (all black ink) is required for review by the Draftsman in response to the instant Office action.

Withdrawn - Objections to the Specification

5. Previous objection to the Abstract for being in an improper format is withdrawn by virtue of Applicants' amendment.

6. Previous objection to the specification for typographical errors is withdrawn by virtue of Applicants' amendment.

7. Previous objection to the specification for confusing descriptions of disclosed sequences, SEQ ID NOs: 5-9 is withdrawn by virtue of Applicants' explanation and by virtue of the amendment to Figure 2.

8. Previous objection to the specification for having inconsistent and unclear data concerning the *ilvH3* and *ilvH4* mutants is withdrawn by virtue of Applicants' amendment supported by experimental data showing which reference was correct and which was a typographical error.

Withdrawn - Claim Objections

9. Previous objection to Claims 1, 3, and 4 for typographical errors is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

10. Previous rejection of Claims 1-2 and 6-8 under 35 U.S.C. § 112, second paragraph, as being indefinite for the exact nature (sequence) of the claimed DNA is withdrawn by virtue of Applicants' insertion of the phrase "wherein the unmutated sequence...is SEQ ID NO:2".
11. Previous rejection of Claims 4-5 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "delete a C-terminal region from the amino acid number 91 **downwards**" (emphasis added) is withdrawn by virtue of Applicants' amendment.
12. Previous rejection of Claim 5 under 35 U.S.C. § 112, second paragraph, as being indefinite for its description of residue 29 is withdrawn by virtue of Applicants' amendment changing the residue in SEQ ID NO:2 to an asparagine as found throughout the specification.
13. Previous rejection of Claims 1-2 and 6-8 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' amendment to Claim 1 limiting the DNA to a specific structure whose function is inherent.
14. Previous rejection of Claims 3 and 6-8 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of Claim 3 and Applicants' amendment to Claim 1 limiting the DNA to a specific structure whose function is inherent.

Maintained - Claim Rejections - 35 U.S.C. § 112

15. Previous rejection of Claims 4-5 under 35 U.S.C. § 112, second paragraph, as being indefinite for the exact nature (sequence) of the claimed DNA is maintained. Unlike the

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amendment to Claims 1, 2, and 6-8, no definition of the unmutated structure has been amended into Claims 4-5. Applicants present no arguments.

16. Previous rejection of Claims 4-5 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants argue only that the rejection has been obviated by an amendment. As noted above in the maintained rejection under 35 U.S.C. § 112, second paragraph, no amendment to include the definition of the unmutated structure has been amended into Claims 4-5. Thus, the previous rejection is maintained.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

17. Previous rejection of Claims 3 and 6 under 35 U.S.C. § 102(b) as being anticipated by *Guardiola et al.* is withdrawn by virtue of Applicants' amendment canceling Claim 3 and amending Claim 6 to only be dependent on Claim 1.

18. Previous rejection of Claims 1 and 6 under 35 U.S.C. § 102(b) as being anticipated by *Smith et al.* is withdrawn by virtue of Applicants' amendment to Claim 1 defining the nature of the unmutated sequence. The teachings of *Smith et al.* no longer anticipated the claimed invention.

NEW REJECTIONS

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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19. Claims 1, 2, 6, 7, 8, 10, and 11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 1, line 2, "which mutation" has no antecedent basis in the claim and is unclear. The Examiner suggests ---which has a mutation selected from the group consisting of---.

20. Claims 12-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is identical to that set forth against claims 4-5 above because the exact nature (sequence) of the claimed DNA is unclear. Unlike the amendment to Claims 1, 2, and 6-8, no definition of the unmutated structure has been amended into Claims 4-5 and 12-18. Applicants present no arguments.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

21. Claims 12-18 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 4-5 and dependent Claims 12-18 have unclear structural limitations

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as noted above in the rejection of Claims 4-5 and 12-18 under 35 U.S.C. § 112, second paragraph.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, the gene encoding the small subunit of acetohydroxy acid synthase (AHAS) isozyme III native to *E. coli* is structurally and functionally described as SEQ ID NO:1 (encoded protein is SEQ ID NO:2), a regulatory subunit subject to feedback inhibition by valine. The gene encoding the large AHAS subunit from *E. coli* is structurally described in the art and functionally described in the specification having the catalytic activity as found on page 6 of the specification. The instant specification also describes particular mutations in SEQ ID NO:1 that encode a small subunit exhibiting reduced valine inhibition (see Table 1 on page 24) when coupled with the catalytic large subunit. In this Table, only a single example of being

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“free from inhibition by L-valine” is demonstrated by pILVH612 (several mutants are described as having reduced valine feedback inhibition). The instant claims are drawn to a genus of DNA encoding **any** small subunit from any source having this same function without any particular structural limitations (limited point mutations relative to SEQ ID NOs:1/2 are required in Claims 4-5). The limited example of particular mutations in SEQ ID NO:1 having this function do not adequately describe the entire genus because the structure of other members of the genus cannot be predicted based on the disclosure since common characteristics among members of the genus have not been described.

Summary of Pending Issues

22. The following is a summary of the issues that must be addressed in response to the instant

Office action:

- a) Formal drawings are required.
- b) Claims 4-5 and 12-18 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the exact nature (sequence) of the claimed DNA.
- c) Claims 1, 2, 6, 7, 8, 10, and 11 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of “which mutation”.
- d) Claims 4-5 and 1-18 stand rejected under 35 U.S.C. § 112, first paragraph, written description.

Allowable Subject Matter

23. As previously noted, DNA encoding the Gly14Asp mutation and the Asn29Lys/Gln92TAG mutations in the *E. coli* AHAS III small subunit (*ilvH* gene - SEQ ID NO:2) are known in the art by virtue of Vyazmensky *et al.* (see IDS #3) and Guardiola *et al.* (see

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IDS #3), respectively. However, Claims 1 and 2 require a mutation at Ser17, which residue is not identified in the art as crucial for valine feedback inhibition in the *E. coli ilvH* gene.

Moreover, while a combination of data presented in Vyazmensky *et al.* and Guardiola *et al.* could produce a mutant of Gly14/Asn29 or Gly14/Gln92 (Claim 4), there is no suggestion or motivation in the art to render such a combination obvious.

Conclusion

24. Claims 1, 2, 4-8, and 10-18 are rejected for the reasons identified in the numbered sections of this Office. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229.

The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK
May 23, 2003